REMARKS

Claims 19-24, 27-46 and 49-65 are pending in the application. With the instant amendment, claims 19, 20, 23, 24, 27, 28, 30-44, 46 and 57 are amended, and withdrawn claims 25 and 26 are amended. Upon entry of this amendment, claims 19-24, 27-46 and 49-65 will be pending in the application.

I. Amendments to the Claims

Claims 19, 20, 23, 24, 27, 28, 30-44 and 46 and withdrawn claims 25 and 26 have been amended to recite "Y is $S(O)_2$." Support for these amendments may be found in the specification, for example, at paragraph [0042] of published application US2004/0180888 A1.

Claim 57 has been amended to correct a typographical error.

II. Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 19-24, 27-46 and 49-65 are rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. The Examiner contends that the claims lack description of how to use the compounds in methods for treatment of an HIV-infection in a host by administering a compound of formula (I). According to the Examiner, the specification only describes a small number of compounds, limited to the embodiment Y = $S(O)_2$ of formula (I), for which binding to glycoprotein or human serum albumin (Table 1) or *in vitro* cell based activity assays are described (Tables 2 and 3). According to the Examiner, Applicants do not have sufficient written description of all embodiments of formula (I) in a method for the treatment of an HIV-infection in a host as claimed. *See* Office Action, pages 3-4.

Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, the claims have been amended to recite in part "[a] method for the treatment of an HIV-infection in a host comprising administering to said host ... an effective anti-HIV treatment amount of a compound of formula (I), ..., *wherein Y is* $S(O)_2$" (emphasis added). Applicants respectfully submit that the rejection is moot with respect to the allegation of lack of written description for embodiments other than Y = $S(O)_2$ of formula (I).

Applicants respectfully traverse the rejection with respect to the Examiner's remaining allegations. Applicants respectfully submit that the specification provides

sufficiently detailed disclosure for those of ordinary skill in the art to conclude the inventor had possession of the methods recited in the amended claims, in particular, the methods for treatment of an HIV-infection in a host by administering an effective anti-HIV treatment amount of a compound of formula (I).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Manual of Patent Examining Procedure ("MPEP") § 2163. For a claim that defines a genus of compounds, such possession is shown by a description of a representative number of species within the genus. *See Enzo Biochem. v. Gen-Probe, Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002). A "representative number" of species is shown when one of skill in the art would recognize that the inventors were in possession of the necessary common attributes or features of the genus claimed. *See Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). However, each species encompassed within the genus need not be disclosed. *See, e.g., In re Bell,* 26 USPQ2d 1529 (Fed. Cir. 1993) and *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994).

According to the Written Description Guidelines provided in the MPEP §2163:

> "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, . . . reduction to drawings, . . . or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Furthermore, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. MPEP § 2163 (citing *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A 1976) ("PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims")). A description as filed is "presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *Id.*, § 2163.04. On the other hand, the claimed invention may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. *Id.*; *see also*

Falkner v. Inglis, 448 F.3d 1357, 79 U.S.P.Q.2d 1001, 1006 (Fed. Cir. 2006) (Indeed, "[a] patent need not teach, and preferably omits, what is well known in the art.") (emphasis added).

Applicants submit that the specification provides sufficiently detailed disclosure for those of ordinary skill in the art to conclude the inventor had possession of the methods of treatment recited in the amended claims.

First, the specification demonstrates Applicants' possession of the genus of compounds described by formula (I) of the amended claims. The specification at paragraphs [0030] - [0080] of published application US2004/0180888 A1 describes dozens of compounds within the genus of formula (I), which share common structural features and common functional characteristics. For example, the compounds of formula (I) share a 3-phenylsulfonylindole scaffold which may be substituted at the 2-position of the indole ring with, for example, an acyl, an amide, an ester, a carboxyl, or a thiocarboxyl group. Compounds of formula (I) also share the common functional characteristic of "displaying significant antiviral activity against HIV, and in particular, strains of the HIV that have developed cross resistance to other anti-HIV drugs" (*see*, for example, the specification at paragraph [0029]). Moreover, compounds of formula (I) "belong to a class of anti-HIV agents that may inhibit reverse transcriptase activity" (*see*, for example, the specification at paragraph [0082]). Synthesis of compounds of formula (I) is described at paragraphs [0462] – [0478] of the specification and in Examples 1-24. In view of the foregoing, Applicants respectfully submit that the application describes sufficient representative species and relevant, identifying characteristics to demonstrate possession of the genus of formula (I), as recited in the amended claims.

Second, the specification demonstrates Applicants' possession of methods of treatment of an HIV-infection in a host by administering a compound of formula (I). Paragraphs [0090] – [0125] explicitly teach that the compounds of formula (I) are useful in the treatment and prophylaxis of an HIV infection, particularly in the treatment of drug-resistant strains of HIV infection. Paragraphs [0449] – [0461] describe pharmaceutical compositions of compounds of formula (I) for administration to humans suffering from the effects of HIV infection. Paragraphs [0449] – [0461] describe administration of pharmaceutical compositions comprising the compounds of formula (I) to humans suffering from the effects of HIV infection. Examples 25 and 26 provide working examples of the ability of a representative number of compounds of formula (I) to protect cells against wild-

type and drug-resistant strains of HIV. Example 25 describes how variations in the substituents on the phenyl ring and at the 2-position of the indole ring affect ability of the claimed compounds to protect cells from HIV-1-induced pathogenicity. Example 26 describes how variations of substituents on the indole ring affect ability of the claimed compounds to protect cells from HIV-1-induced pathogenicity.

The Examiner alleges that Tables 2 and 3 of Example 25 and 26, respectively, "[disclose] a small number of compounds," and that as such, "applicants do not have sufficient written description of all embodiments of formula (I) in a method for the treatment of an HIV-infection in a host as claimed." *See* Office Action, pages 3-4. Applicants respectfully disagree and submit that one of ordinary skill in the art would recognize that the exemplary compounds described in Examples 25 and 26 are representative of the genus of compounds described by formula (I) of the amended claims, especially in view of the Examples' description of how variations of substituents on the phenyl ring and indole ring affect ability of the claimed compounds to protect cells from HIV-1-induced pathogenicity. Accordingly, Applicants respectfully submit that there is sufficient written description in the specification to convey to a person of ordinary skill in the art that Applicants had possession of the claimed invention at the time of the application.

In view of the specification's teaching of hundreds of compounds within the genus of formula (I), of which a representative number are shown to protect cells from the HIV-1 induced pathogenicity of both wild-type and drug resistant HIV-1 strains, Applicants respectfully submit that one of ordinary skill in the art have no reason to conclude that Applicant's did not have possession of methods of treatment of an HIV-infection in a host by administering a compound of formula (I) as recited in the amended claims. Respectfully, the Examiner is reminded that the Patent Office bears the burden of presenting evidence why the written description is inadequate. *Wertheim*, 541 F.2d at 263. Consequently, Applicant respectfully requests that the rejection of claims 19-24, 27-46 and 49-65 under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement be reconsidered and withdrawn.

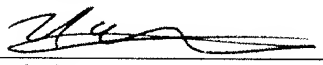
CONCLUSION

Applicants believe that the claims of the instant amendment meet all of the conditions for patentability and are in condition for allowance. Accordingly, an early indication of the same is respectfully requested.

No fee other is believe to be due in connection herewith. However, should the Patent Office determine otherwise, please charge the required fee to Jones Day deposit account no. 50-3013 (referencing 417451-999076).

Respectfully submitted,

Date: July 1, 2008



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